REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and following remarks.

This amendment adds, changes, and/or deletes claims in the application. Claims 9, 11-12, 14, and 16 are currently being amended. Claims 46-52 are being added. A detailed listing of all claims that are, or were, in the application is presented herein.

Upon entry of the foregoing amendments, claims 9-12, 14, 16, and 46-52 will be pending and under examination. Claims 1-4, 6, 8 , 13, 15, 18-34, and 41-45 will be pending, but withdrawn from examination.

I. Support for Claim Amendments

The following table details exemplary support for each claim amendment or new claim in the specification, as filed.

Claim	Exemplary Support in Specification
9	Page 5, lines 12-20; Example 10, Table 5; page 28, lines 24-30; page 31, lines 17-20.
10-11	Clarifying amendment only
12	Page 3, lines 12-24 and throughout specification
14	Page 5, lines 21-32; page 6, lines 1-7; Examples 10-11
16	Page 3, lines 12-24 and throughout specification
46	Page 5, lines 21-32; page 6, lines 1-7; Examples 10-11
47	Page 5, lines 11-31; Examples 10-11
48	Page 5, lines 12-20; Example 10
49	Page 5, lines 12-20; page 31, lines 17-20
50	Pages 54-55, Table 4
51	Page 55, Table 5
52	Page 5, lines 21-32

II. The Claims are Definite, in Accord with 35 U.S.C. § 112, Second Paragraph

Claims 12, 14, and 16 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Examiner stated that: (a) it was difficult to discern what element induces the CTL response in claim 14, and (b) claims 12 and 16 "fail to set forth clear discrete process steps." Applicants respectfully traverse the rejection.

Without acquiescing to the rejection, Applicants have made clarifying amendments to the claims, rendering the rejection moot. As amended, claim 14 recites that the "5T4 antigen is a modified 5T4 antigen comprising an HLA CTL peptide epitope of 5T4 antigen." Thus, the relationship between the "modified 5T4 antigen" and "HLA CTL peptide epitope" are clear. Also, claims 12 and 16 clearly recite the process step of "immunizing the subject with 5T4 antigen."

Therefore, the claims comply with the "definite claiming" requirement of 35 U.S.C. § 112, second paragraph, and Applicants respectfully request withdrawal of the rejection.

III. Claim 14 Complies with the "Written Description" Requirement of 35 U.S.C. § 112, First Paragraph

Claim 14 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that the specification does not adequately describe. In particular, the Examiner asserted that the "claim encompasses a method of employing a 'peptide epitope' of an antigen," and that the epitope is undefined outside of its generic meaning. The Examiner further stated that "the specification provides a description of the 5T4 antigen and uses thereof," as opposed to peptide epitopes. Applicants respectfully traverse the rejection.

First, claim 14 recites the step of immunizing a subject with a "modified 5T4 antigen comprising an HLA CTL peptide epitope," and not with a "peptide epitope" *per se*. As already acknowledged by the Examiner, the specification provides a description of 5T4 antigens and uses therefore. *See* Office Action, page 4, first paragraph.

Second, the specification provides adequate description of peptides that comprise HLA CTL epitopes. At page 6, lines 1-7, the specification states that peptides of the present invention advantageously comprise HLA CTL epitopes of 5T4. This same passage provides

instruction on how to identify such epitopes in a 5T4 polypeptide, and how to modify such epitopes. In particular, the specification teaches that peptides can be screened for superior HLA/CTL binding capabilities using the publicly-available computer program "Peptide Binding Predictions," devised by K. Parker at the National Institutes of Health (page 6, lines 1-7; page 27, lines 6-9).

Example 10 demonstrates the use of this program to identify HLA CTL epitopes on both human and murine 5T4. The Example provides 23 representative peptides comprising HLA CTL epitopes. Moreover, Example 11 demonstrates that the program identifies peptide modifications that significantly improve HLA binding. In one case, the program identified two amino acid changes that increase by 10-fold a 9mer's half time of dissociation from HLA A0201. In another case, the program identified two amino acid changes that increase by 4-fold a 9mer's half time of dissociation from HLA A0201.

Accordingly, the specification provides adequate description of peptides comprising HLA CTL epitopes, including disclosure of a representative number of species. Therefore, Applicants respectfully request withdrawal of the rejection.

IV. The Claims are Patentable over U.S. Patent 5,869,053 (Stern et al.)

Claims 9-12, 14, and 16 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent 5,869,053 ("the '053 patent"). Applicants respectfully traverse this rejection.

The '053 patent describes a human 5T4 glycoprotein and 5T4 antibodies. It indicates that one use for 5T4 antigens and antibodies is "in the production of vaccines." *See* paragraph spanning columns 2-3. In that regard, the '053 patent states that 5T4 antibodies "are of interest . . . in the development of contragestational vaccines since the antigen is expressed very early on in pregnancy." *See* column 3, lines 4-7. Contragestational vaccines are the only type of vaccine described by the patent, however.

The claims are patentable over the '053 patent because the patent neither teaches nor suggests that: (a) non-human 5T4 antigens can be used in a vaccine or (b) 5T4 antigens induce an anti-tumor immunotherapeutic response.

The '053 patent's disclosure is limited to a human 5T4 glycoprotein; the patent neither teaches nor suggests that 5T4 exists in non-human species. Furthermore, given the '053 patent disclosure, it would not be obvious that 5T4 proteins exist in other species and are useful in human vaccines. Many human proteins lack non-human counterparts. Additionally, non-human proteins frequently differ immunologically from their human counterparts.

The '053 patent also lacks any teaching or suggestion that 5T4 antigens induce an anti-tumor immunotherapeutic response. The patent only describes anti-5T4 antibodies in the context of diagnostic applications, drug-targeting applications and contragestational vaccines. "Contragestional vaccines" refers to vaccines that sensitize a maternal immune system to terminate a pregnancy. Clearly, pregnancy and cancer are vastly different medical conditions, and the teaching of a contraceptive method does not suggest a cancer treatment method.

As the '053 patent does not teach or suggest the claimed invention, withdrawal of this ground for rejection is respectfully requested.

V. Conclusion

The present application is now in condition for allowance, and favorable reconsideration of the application is respectfully requested. If the Examiner believes that an interview would advance prosecution of the application, she is invited to contact the undersigned by telephone.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of

papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 19, 2003 By Michele M. Simkin

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